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An Intervention Study to Prevent Relapse in Patients With Schizophrenia

B. van Meijel, C. Kruitwagen, M. van der Gaag, R.S. Kahn, M.H.F. Grypdonck

Purpose: To determine whether the use of relapse prevention plans (RPPs) in nursing practice is an effective intervention in reducing relapse rates among patients with schizophrenia.

Design and Methods: Experimental design. Patients with schizophrenia (or a related psychotic disorder) and nurses from three mental health organizations were randomly assigned to either an experimental (RPP) or control condition (care as usual). The primary outcome measure was the psychotic relapses in the research groups.

Results: The relapse rates in the experimental and control groups after 1-year follow-up were 12.5% and 26.2%, respectively ($p=.12$, ns). The relative risk of a relapse in the experimental versus the control group was 0.48(ns).

Conclusions: In this study no statistically significant effects of the intervention were found. Effectiveness research in this area should be continued with larger sample sizes and longer follow-up periods.

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[Key words: schizophrenia, psychosis, relapse, early recognition, early intervention, self-management]

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Schizophrenia is a psychiatric disorder that is usually chronic. Periods of relative stability alternate with periods in which psychotic symptoms are prominent. For such patients and the people in their surroundings, psychosis is generally a great burden. The person is anxious and confused; social relations become disturbed; dependence on care services increases; and social recovery can last from months to years.

The prevention of psychotic relapses receives much attention in present treatment programs. According to current scientific knowledge, the combination of pharmacologic therapy and psychosocial interventions is the most effective way to prevent psychoses (American Psychiatric Association [APA], 2003). Nevertheless, the annual percentage of relapses under present treatment conditions is around 35%. According to many authors, this percentage is unnecessarily high, and every effort should be made to further optimize treatment (Ayuso-Gutierrez & Del Rio Vega, 1997; Bellack & Mueser, 1993; Kissling, 1991, 1992; van Meijel, 2003; van Meijel, van der Gaag, Kahn, & Grypdonck, 2004). The relapse percentage could be further reduced, perhaps to about 15% to 20%.

This article concerns a psychosocial intervention that has the objective to contribute to the prevention of psychotic relapses. The intervention consists of the early recognition of the early signs of psychosis. These early signs are changes in the experiencing, thinking, and behavior of a person in

the preliminary phase of psychotic relapse. When the recognition of early signs is adequate, measures can be taken to prevent a psychotic crisis.

The expectation is that early recognition and early intervention are readily applicable to nursing care. Nurses have frequent contact with patients and family members and so can observe the patient's condition. Van Meijel, van der Gaag, Kahn, and Grypdonck (2002a, 2002b) studied the existing early recognition and early intervention practices in the Netherlands. These practices included the preparation of relapse prevention plans in conjunction with a patients and members of their social networks. This plan includes detecting the early signs of difficulty and actions that could

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be taken when psychotic relapse threatens. The results from this study, in combination with the results of a review of the literature (van Meijel et al., 2004), were used to devise an intervention protocol for the preparation of relapse prevention plans with schizophrenic patients in nursing practice. In the design phase, the intervention was evaluated by experts and by means of case studies (van Meijel, van der Gaag, Kahn, & Grypdonck, 2003b). The definitive version of the protocol was then established.

In this article, we describe the research into the effectiveness of the intervention protocol. The research question for this study was: "Do patients with schizophrenia and related psychotic disorders, with whom the relapse prevention plans are applied have less chance of undergoing a psychotic relapse than do patients who receive care as usual?" Secondarily, we study the effects of working with relapse prevention plans on (a) the insight of the patient into the illness, (b) the working alliance between patient and nurse, and (c) the use of medication.

Description of the Intervention

The intervention protocol gives step-by-step instructions to nurses on how they can systematically prepare a relapse prevention plan with a patient and with members of the patient's social network (van Meijel, van der Gaag, Kahn, & Grypdonck, 2000; van Meijel et al., 2003a). This protocol includes four successive phases.

First, in the preparatory phase, information is offered to patients and the participating members of the social network. The objective is to arrive at a joint basis for working with a relapse prevention plan. Nurses make a systematic assessment of factors that can promote or hinder working with a relapse prevention plan and try to influence these factors favorably, for example, with additional psychoeducation if a lack of knowledge about schizophrenia and psychoses is apparent.

Second, the early signs are systematically inventoried. This inventory is compiled as much as possible within the triad of patient members of the social network, and caregiver(s). The early signs are then defined operationally at three levels of severity: level 1: normal and stable; level 2: light to moderate; and level 3: serious.

Third, in the monitoring phase, patients and others involved receive instructions and assistance in the recognizing and scoring the early signs listed. The fourth phase is the preparation of an action plan. Actions are formulated that can be performed by the participants when a psychotic relapse threatens. These actions are related to managing stress, enhancing coping, and applying protection from the surroundings.

Methods

A randomized controlled trial with a follow-up period of 1 year was selected as the research design. Patients were in-

cluded if, according to the treating psychiatrist, they met the diagnostic criteria of schizophrenia or a related psychotic disorder according to the Diagnostic and Statistical Manual of Mental Disorders (APA, 1994). The patient had to be stabilized to the extent that he or she could collaborate in the preparation of the relapse prevention plan. In operational terms, this means that none of the items of the Positive Scale of the Positive and Negative Syndrome Scale (PANSS; Kay, Opler, & Fiszbein, 1987) was higher than 4. The patients could be hospitalized, be attending the day clinic, or be treated as outpatients. Outpatients had to have a minimum contact frequency of once every 2 weeks in the phase of the preparation of the relapse prevention plan. Finally, the patient had to be able to give informed consent to participate in the study.

Patients were excluded if they had organic brain disorder or mental retardation. Further exclusion criteria were alcohol or drug abuse accompanied by serious communication or behavioral problems. Patients who had participated the previous year in the Liberman module "Symptom Management" were also excluded. The content of this module is similar to the content of the intervention protocol. Patients who had previously been involved with other forms of early recognition and early intervention were also excluded.

Participants came from three mental health organizations: an institution for outpatient care and two mental health organizations with inpatient, day-clinic, and outpatient care. The research protocol was designed for randomization of the nurses and patients. Administrators of the various departments compiled a list of nurses to be considered for participation in the study. The selection criterion was that nurses were capable of exercising the responsibility for the total nursing care of the patients and their social network. The selected nurses were then divided at random per department between the experimental and the control conditions. By randomization at the departmental level, specific characteristics of the department and the treatment could be divided equally over both research conditions. The nurses then listed the patients under their care who met the selection criteria. To avoid a selection bias, the researcher determined at random the order in which the patients would be approached for participation in the study. Ultimately, 1 to 3 patients were selected for each nurse to participate.

Procedure and Data Collection

The nurses who had been assigned to the experimental group were trained in the application of the intervention protocol in two training sessions. During these sessions, the underlying theory was explained, and role-playing exercises were used to practice the intervention. A large majority of the participating nurses said at T2 that these two training sessions were sufficient for proper execution of the intervention protocol (van Meijel et al., 2003b). For the nurses in the control group, an information session was held in which they were informed in broad outlines about the research objectives and procedures.

Table 1. Overview of Measurements

Variable	Instrument	T 1	T 2	T 3
Nurse				
Demographic data	Registration form (N)	X		
Training and work experience	Registration form (N)	X		
Patient				
Demographic data	CASH (R)	X		
Illness history	CASH (R)	X		
Psychopathology	PANSS (R)	X		
Psychiatric diagnosis	DSM-IV (D)	X		
Medication	Patient dossier (N)	X	X	X
Insight into psychosis	Insight Scale SR (P)	X	X	X
Insight into psychosis	Insight-Scale I (N)	X	X	X
Psychotic relapse	PANSS - PS (R)		total follow up	
Treatment setting	Registration form (N)	X	total follow up	
Patient – nurse				
Working alliance	WAI (P)	X	X	X

Note. N=Nurse; P=Patient; D=Doctor; R=Researcher

Data collection then took place at three times: (a) T1: after completion of the training sessions. This is when the patients were selected. (b) T2: after completion of the relapse prevention plans or a corresponding period in the control condition. (c) T3: after completion of the follow-up period of 1 year. **Table 1** shows an overview of the measurements at the various times.

For both conditions, the recruitment and selection procedure of patients commenced after the completion of the training and information trajectory. The patients selected were first asked by supervising nurses to participate in the study. If the patients agreed, they were visited by the researcher or a research assistant, who provided them with further information about the study and the informed-consent procedure. After definitive agreement, the T1 data were collected.

Nurses of the experimental group prepared the individualized relapse prevention plans with the patients and, if possible, with members of the patient's network. The control group received care as usual. The nurses were instructed to continue their care as usual, with the explicit instruction not to use any structured methods for early recognition and early intervention. After completion of the relapse prevention plans in the experimental group, and after a comparable period of care as usual in the control group, the T2 measurements were recorded. Then the follow-up period began in which the relapse prevention plan was applied in the experimental group. Nurses and patients were instructed to score the early signs in the plan each week. They had to act according to the relapse prevention plan when these early signs increased. In the control condition, care as usual was continued. At the end of the follow-up year, T3 measurements were taken.

Registration of Relapses

Evaluation of a psychotic relapse was made in consultation between nurse and psychiatrist. A psychotic relapse was

indicated by a significant increase of the following psychotic symptoms: (a) delusions, (b) hallucinations, (c) disorganization of thinking, which may be in combination with (d) chaotic or aggressive behavior. In addition to this clinical judgment, the CGI (Clinical Global Impression) was also scored (Guy, 1976). As the criterion for relapse, we took a score of 6 or higher on the Global Impression Scale, which means that a severe to very severe deterioration of the general condition of the patient had occurred because of the psychotic symptoms. Further, the psychotic symptoms had to be present for at least 7 days to be considered a relapse.

The written report of the psychotic relapse on the progress-report form also indicated whether patients had received a higher dose of antipsychotic medication and whether they had been admitted to hospital. When the report was received, an independent researcher, who did not know the research condition of the patient, interviewed by telephone the nurse or caregiver who had been able to observe the patient during the psychotic episode. The interview was structured on the basis of the items of the Positive Scale of the Negative Syndrome Scale (PANSS). This score was compared with the PANSS score on T1 to assess the relative increase of psychotic symptoms.

Instruments

For research into the psychopathologic characteristics of the patient, the PANSS was used in this study (Kay, Fiszbein, & Opler, 1987). The scale was tested extensively for validity and reliability with satisfactory results (Kay et al., 1987). Both the main researcher and the research assistant received PANSS training.

Insight into the illness of the patient was measured with the Insight Scale (Birchwood et al., 1994). This self-report scale consists of 8 items for three dimensions of insight: (a) attribution of symptoms (two items), (b) awareness of illness (two items), and (c) need for treatment (four items). The psychometric aspects of this scale are satisfactory (Cronbach's $\alpha = .75$, test-retest reliability = .90). The scale was first translated into Dutch by Van der Gaag, Bervoets, and De Boer in 1994.

The quality of the therapeutic alliance was measured with the Working Alliance Inventory (WAI; Horvath & Greenberg, 1989). This scale was translated into Dutch by Vervaecke & Vertommen (1993). It distinguishes three dimensions based on Bordin (1976): (a) the goal dimension: the agreement between patients and caregivers about the goals being worked for (12 items); (b) the task dimension: the agreement between patients and caregivers about the way in which the objectives can be achieved (12 items); and (c) the bond dimension: the development of a personal bond between patients and caregivers (12 items). Psychometric research has provided indications of sufficient validity and reliability of the scale. For this study, we used the client version of the scale.

The Clinical Global Impression (CGI; Guy, 1976) consists of two simple subscales to measure the Severity of Illness and the Global Impression, respectively. For our research

purposes we used only the Global Impression Scale, which pertains to changes over the course of time. The scale is structured symmetrically: from 1 (very much improved) to 4 (no change) to 7 (very much worse).

The Comprehensive Assessment of Symptoms and History (CASH; Andreasen, Flaum, & Arndt, 1992) is a comprehensive diagnostic instrument to compile data on a large number of illness-related subjects. For our study, we used sections 1 (socio-demographic data) and 4 (illness history).

For the antipsychotic medication, dosage equivalents were calculated with respect to haloperidol (Ziekenfondsraad, 1999). The use of sedatives was scored dichotomously.

Data Analysis

For the comparisons of experimental and control groups, we used the Chi-square test, the Mann-Whitney *U* test, and the *t* test for independent groups in accordance with the measurement level and the group sizes. To estimate the treatment effect, many risk measures were also used.

To compare the "survival duration" of the patients in the two groups, that is, the period that they are free of psychosis, a survival analysis was performed (Kaplan Meier/Log rank test/Cox proportional hazard regression). Longitudinal changes in medication use, illness insight, and the quality of the therapeutic alliance as well as comparison of changes between the two groups were studied by means of Repeated Measures ANOVA and multilevel analysis.

Results

The Nurses

The basic data were collected from the caregivers who had completed at least the period T1-T2. The total number was 48, including 26 in the experimental group and 22 in the control group. Most of them had nursing backgrounds ($n=45$). The rest ($n=3$) were social workers. The groups did not differ by age, sex, education, duration of employment, or years of experience.

Dropouts

At T1, a total of 95 patients were included: 51 in the experimental group and 44 in the control group. In the T1-T2 period, that is during the phase of drawing up a relapse prevention plan, 11 patients dropped out from the experimental group and 2 from the control group. The reasons for dropping out of the experimental group were: premature discharge ($n=1$); stress caused by preparing the relapse prevention plan ($n=2$); psychotic relapse ($n=1$); lack of motivation to prepare the relapse prevention plan ($n=5$); and lack of time of the nurses ($n=2$). The reason for dropping out of the control group was completion of the treatment ($n=2$).

We tested whether the dropouts and the remaining patients differed on all T1 variables. The dropouts scored significantly lower on the Global Assessment of Functioning Scale of the DSM-IV diagnoses ($U=143$; $p<.05$), which in-

dicates a lower general level of functioning. Further, their total PANSS scores were significantly higher ($U=254$; $p<.05$). On the PANSS subscales, the higher scores were found on the General Psychopathology Scale ($U=261.5$; $p<.05$) and the Negative Scale ($U=329$; $p<.05$), but not on the Positive Scale ($U=452$; ns).

Baseline Measurements

Table 2 shows an overview of the baseline measurements (T1). No significant differences were found for any of the variables between the experimental and control groups, with

Table 2. Baseline Comparisons

Variable	Experimental group ($n=40$)	Control group ($n=42$)	Test	<i>p</i>
Age, mean	35.2	34.5	$t_{(80)}=-.345$.73
Male sex	28 (70%)	37 (88%)	$\chi^2_{(1)}=4.082$.04
Marital status: single	33 (83%)	32 (76%)	$\chi^2_{(1)}=.496$.48
Dutch nationality	37 (93%)	39 (93%)	$\chi^2_{(1)}=.004$.95
Educational level				
Primary school or lower vocational school	15 (38%)	24 (57%)	$\chi^2_{(1)}=3.170$.08
Other education	25 (62%)	18 (43%)		
Paid employment	5 (13%)	12 (29%)	$\chi^2_{(1)}=3.220$.07
Organized activities	16 (40%)	15 (36%)	$\chi^2_{(1)}=.160$.69
DSM - 1				
Schizophrenia	24 (60%)	33 (79%)	$\chi^2_{(2)}=3.345$.19
Schizo-affective disorder	11 (28%)	6 (14%)		
other psychotic disorders	5 (12%)	3 (7%)		
DSM-5 mean	56.3	58.8	$t_{(80)}=1.032$.31
Care intensity				
Ambulatory care	28 (70%)	33 (79%)	$\chi^2_{(2)}=1.648$.44
Semimural care	5 (12.5%)	2 (5%)		
Clinical care	7 (17.5%)	7 (16%)		
Age at onset mean	23.1	23.5	$t_{(80)}=.315$.75
Sickness duration in years:				
mean	12.2	11.0	$t_{(80)}=-.589$.55
Number of psychoses:				
mean	4.4	3.8	$t_{(80)}=-.612$.54
Medication: haloperidol equivalents: mean	5.1	5.5	$t_{(80)}=.505$.62
Sedatives	13 (33%)	19 (45%)	$\chi^2_{(1)}=1.199$.28
PANSS total: mean	63.9	60.4	$t_{(70)}=-1.037$.30
PANSS Positive Scale:				
mean	13.7	12.2	$t_{(79)}=-1.599$.11
PANSS Negative Scale:				
mean	15.6	15.9	$t_{(77)}=2.254$.80
PANSS- General	34.1	31.6	$t_{(73)}=-1.528$.13
Psychopathology: mean				
Insight Scale - SR: mean	10.4	9.66	$t_{(72)}=-1.182$.24
Insight Scale - I: mean	10.3	10.7	$t_{(74)}=.805$.42
WAI: mean	134.1	133.8	$t_{(73)}=-.085$.93

the exception of the variable of sex. The experimental group had more women than men ($X^2_{(1)}=4.082$; $p<.05$).

Relapses

In the experimental group, 40 relapse prevention plans were prepared. The average number of days devoted to this preparation was 155 ($SD=94$). The corresponding period of nonintervention in the control group was on average 145 days ($SD=70$), a nonsignificant difference ($t_{(80)}=-.549$; ns).

The frequency of scoring of the early signs in the experimental group indicated a slight decline in the course of the follow-up year, but the average was between 5 and 9 scores per quarter for the entire year. Six patients did not score any longer by the end of the follow-up year: three for lack of motivation, one because of a long-term psychosis, one because of detention, and the sixth because things were going well with her and she did not see the need for regular scoring. Table 3 shows an overview of the relapse rates in the two groups.

The relapse rates in the experimental and the control groups were, respectively, 12.5% and 26.2%. Testing showed that this difference was not statistically significant ($X^2_{(1)}=2.445$; $p=.12$). In addition to the conventional testing with the Chi-square test, other measures were calculated to give an indication of the treatment effect. The Relative Risk (RR) of a relapse in the intervention group with respect to the risk in the control group was 0.48 ($CI\ 95\%: 0.20<X<1.26$). The Relative Risk Reduction (RRR) was 0.52 ($CI\ 95\%: -0.26<X<0.80$), which means that the chance of a relapse declined by 52% by application of the intervention. The Absolute Risk Reduction (ARR) was 0.137 ($CI\ 95\%: -0.031<X<0.305$), which implies that a relapse can be prevented with the intervention protocol in almost 14 patients out of a 100. The Number Needed to Treat (NNT) is 7.3 ($CI\ 95\%: 3.28<X<8$), indicating that the intervention must be applied to at least 7 patients to prevent a psychotic relapse in one of them.

The Figure shows the Kaplan-Meier survival curves for the experimental and the control groups for the follow-up period of 1 year. Survival refers to the period the patients were free of psychosis. The mean survival time of the experimental group was 329 days, and 296 days for the control. The Log Rank Test revealed no significant differences ($Log\ Rank_{(1)}=2.28$; $p=.13$).

The scores on the PANSS-Positive Scale increased for the decompensating patients in the control condition from 14.1

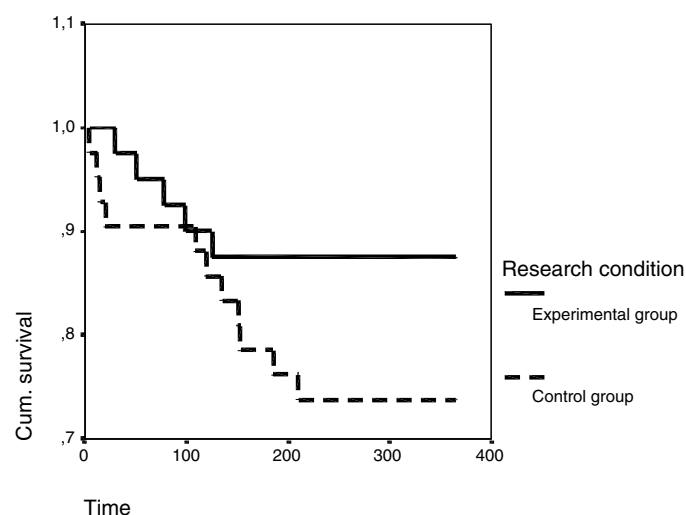


Figure. Survival curves: The period patients were free of psychosis.

at baseline measurement to 26.4 at the time of psychotic relapse) (Wilcoxon Signed Ranks Test $z=2.371$; $p<.05$) and for the decompensating patients in the experimental condition from 17.2 to 30.2 (Wilcoxon Signed Ranks Test $z=2.023$; $p<.05$). This increase was significant in both groups. With two exceptions, one in the control group and one in the experimental group, all patients who had a relapse were prescribed higher dosages of medication. All patients from the experimental group were admitted to the clinic because of the relapse. In the control group, two of the patients received intensive home care to cope with the crisis; six were admitted to an intensive clinical care unit, and three others were already receiving clinical care at the time of the relapse.

Other Variables

With regard to the consuming medication, no significant time or intervention effects were found ($p>.10$). Thus, application of the intervention did not lead to significant changes in medication consumption. This result applied also for the total scores on the Insight-Scale IS, both for the self-report version and for the informant version. In the three subscales of the IS, a significant effect was found on the subscale "attribution of symptoms" of the self-report version ($p=.04$).

The measurements on the Working Alliance Inventory showed significant time-intervention interaction effects on the total score ($p=.03$), on the goal dimension ($p=.05$), and on the bond dimension ($p=.02$). As indicated by the average scores of these variables, the significant effects can be explained primarily by the relatively irregular score pattern within the control group and relatively stable scores within the experimental group. These differences make interpretation of the scores difficult.

Discussion

This study was conducted to test the effects of a nursing intervention with the objective to prevent psychoses in patients

Table 3. Relapse Outcomes

	Experimental group	Control group	Total
Relapse			
No	35 (87.5%)	31 (73.8%)	66
Yes	5 (12.5%)	11 (26.2%)	16
Total	40 (100%)	42 (100%)	82

$p=.12$.

with schizophrenia or related disorders. The randomized controlled trial included stabilized patients who met the diagnostic criteria of schizophrenia or a related schizophrenic disorder. The dropout in the experimental group puts into question the comparability of the experimental and control group. With a dropout rate of 22% the effects of randomization on achieving comparability between experimental and control condition is put in jeopardy. However, the comparison of experimental and control groups excluding the patients who dropped out, showed that those who remained in the groups were comparable. In addition, those who remained in the experimental group had somewhat less favorable means than the remainders in the control group on those variables in which dropout and the remaining patients differ. When comparing the baseline measurements with all the patients who were included, the patients in the experimental group had a significantly lower level of general functioning than did the patients in the control group ($t_{(86)}=2.028$; $p=.046$). Therefore differences in the groups as a probable alternative explanation of the findings is not likely. Apparently, the randomization did not result in comparable groups at the moment of inclusion, and correction may have been needed if all patients remained in the study.

The relatively high dropout rate in the experimental group showed that the efforts involved in preparing a relapse prevention plan cannot be sustained by all of the patients or nurses. The patients who dropped out had a significantly lower level of general functioning and more psychopathologic symptoms. Women were significantly overrepresented in the experimental condition, which could have slightly distorted the results because the disease process in women is, in general, slightly more favorable than in men. For all the other variables, the two groups were comparable.

The reliable measurement of psychotic relapse is not without problems. Linszen (1993) showed in a review of the literature how different the definitions and measurements of psychotic relapse are. Sometimes, clinical readmission suffices as the criterion. However, this is not an adequate criterion because schizophrenic patients can be admitted for a very wide range of reasons. In other studies, clinical judgment is used as the criterion: a relapse occurs when the caregivers call it one. A scientifically more justified measurement is obtained when testing is done with regularity on the basis of relapse criteria prepared in advance, with the aid of validated measurement instruments such as the PANSS.

In our study, we sought a compromise that was compatible with the logistic efforts that could be carried out at the three locations where the research was conducted. This compromise consisted of the clinical judgment of the caregivers, the score on the CGI, the 7-day criterion, and the interview with the caregivers by a research assistant who was blinded to the research condition of the patient. This procedure was combined with a 3-month contact with the nurse in which all the information regarding the course of the illness was again checked. The significant increase of psychotic symptoms in relapsed patients confirmed that, with the criteria selected, we were indeed able to track the most serious re-

lapses. A potential problem seems rather to be in the cases in which the caregivers decided that the criteria were not met by a small margin and so decided not to report the change in the status of the patient. Periodic measurements with established relapse criteria could resolve this problem but this would require, as noted, a much greater research capacity.

In view of the relapse outcomes in both groups, results were in the desired direction but this difference was not statistically significant. The relapse rate in the experimental group was low (12.5%), consistent with results of studies with optimal treatment conditions. Even the relapse percentage in the control group might be considered low for regular treatment conditions, generally estimated at about 35% (Ayuso-Gutierrez & Del Rio Vega, 1997; Kissling, 1991; Kissling, 1992; Liberman & Kopelowicz, 1995; Tarrier, 1997; Viguera, Baldessarini, Hegarty, Kammen, & Tohen, 1997; Wirshing, Eckman, Liberman, & Marder, 1991).

A contamination effect between the experimental and the control groups cannot be excluded. Randomization at the unit level inadvertently has the result that experimental-group nurses communicate with control-group nurses about the research and the intervention, which could have positive effects on the control groups. In both groups, specific effects could have occurred alongside the therapy-related effects such as the Hawthorne effect: the extra attention that nurses and patients received because of their participation in the study could have generated treatment effects independent of the specific intervention.

The sample size must also be discussed. In the design of the study, relapse rates of 15% (experimental group) and 40% (control group) were predicted when the sample size was determined. A size of 48 people per group would then suffice ($\alpha=.05$; $\beta=.80$). Although the sample was smaller than expected, the lower than expected relapse rate in the control group (26%) could have been one of the reasons the proportional differences were not statistically significant. A considerably larger sample is needed for significance given these relapse rates.

In our opinion, the intervention studied here can be viewed as part of a more comprehensive treatment program in which other components also contribute to reducing psychotic recidivism. Included, of course, are pharmacologic therapy and various forms of skill training, supportive family therapy, and cognitive therapy. The combined application of these interventions will achieve the most favorable treatment results.

We expected that the intervention would generate increased insight into the illness, that the working alliance would change between patient and nurse (in particular in the task and goal dimensions), and that lower doses of medication would be prescribed because of the reduction of psychotic relapses. The multilevel analysis led to the conclusion that significant differences existed regarding the work alliance (total score, bond, and goal dimension) and the insight and attribution of symptoms. However, the interpretation of these results is difficult because they were influenced

primarily by a relatively irregular score pattern at various times in the control condition.

The possibilities of comparing our research results with results of other studies are few. Methods of early recognition and early intervention have indeed been used in various studies, but mostly in combination with divergent medication strategies, whereby the specific effect of early intervention could not be determined. An exception is the study of Herz et al. (2000). They standardized the medication administration and examined the effects of a program for relapse prevention. They compared this intervention program with a control condition in which care as usual was offered. Active monitoring of early signs was combined with psychoeducation and weekly group therapy for patients and family meetings (multifamily groups). After 18 months, they found significant differences between the two groups in psychotic relapses and rehospitalizations. Also of relevance is the study of the effects of the Libermann Modules, with modular treatment in group therapy oriented to various skill areas. The "Symptom Management" module is directed to early recognition of psychotic relapse. These modules have been shown to have positive effects on the acquisition of new knowledge and skills (Eckman et al., 1992; Goulet, Lalonde, Lavoie, & Jodoin, 1993; Wallace & Liberman, 1995; Wallace, Liberman, MacKain, Blackwell, & Eckman, 1992). The effect on rehospitalizations was studied by Stenberg, Jaaskelainen, and Royks (1998), who concluded that the training had no significant effect on the number of readmissions but did have an effect on their duration.

Conclusions

In this study, the intervention and control groups showed clinical difference that did not reach the level of statistical significance. Reasons for these results indicated that effectiveness research should be continued on psychotic relapse. Much uncertainty still exists about the effectiveness of early intervention strategies in relation to relapse outcomes. The intensification of research in nursing practice is of great importance because a considerable portion of the therapeutic efforts is and can be executed with the context of nursing care.

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